Doc Code: AP.PRE.REQ

PTO/SB/33 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 207,565

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/577,408	April 25, 2006

First Named Inventor: Cilurzo

Art Unit	Examiner
1612	SUTTON, Darryl C.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 24,156.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/Jay S. Cinamon/
Signature

Jay S. Cinamon
Typed or printed name

212-885-9232
Telephone number

November 29, 2011
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 3 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Cilurzo et al.	Confirmation No.:	1408
Serial No.:	10/577,408	Art Unit:	1612
Filed:	April 25, 2006	Examiner:	SUTTON, Darryl C.
		Attorney Docket No.:	207,565
Title:	"Self-supporting films for pharmaceutical and food use"		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants request review of the final rejection in the above identified application. No amendments are being filed with this request. This request is being filed with a Notice of Appeal. The review is requested for the reasons stated below. Claims 1-5, 12-14, 16, 17 and 21-24 are pending and stand rejected.

Claim 1 is drawn to self-supporting films consisting essentially of: a) between 40 and 80% by weight of a filmogenic substance consisting of a maltodextrin, b) between 15 and 55% by weight of a plasticiser, c) between 0.05% and 30% by weight of an active ingredient for food or pharmaceutical use, on the total weight of said films, wherein said films are free from hydrocolloids.

1. Rejection under 35 U.S.C. §103(a) as being unpatentable over Barkalow et al. (US 2004/0096559) in view of Chen et al. (US 2003/0068378)

According to the Office (p. 4, Office Action, June 2, 2011, "OA3"), "While the Examiner agrees that the inclusion of **maltodextrin as a hydrocolloid** in the disclosure of Chen etal. seems to be **misplaced**, the Examiner is interpreting maltodextrin's inclusion as a useful film forming agent as an admission by Chen et al. that, at the least, maltodextrin can be used as an equivalent to the hydrocolloids in the production of the edible films of Chen et al." [emphasis added]

In fact, the Applicants clearly demonstrated (pp. 6-9, Reply, April 21, 2011) that maltodextrin in Chen et al. has not been simply misplaced, but indeed improperly and erroneously included maltodextrin among the hydrocolloids. The latter as well as other technical errors present in Chen et al. were already discussed (pp. 6-9, Reply, April 21, 2011). In this regard, the Office has provided no technical reasoning or evidence to explain how maltodextrin and hydrocolloids are equivalent in view of the proved difference between each other.

Furthermore, the Office provided no citation to Chen et al. to support the assertion that "maltodextrin's inclusion as a useful film forming agent as an admission by Chen et al. that, at the least, maltodextrin can be used as an equivalent to the

hydrocolloids in the production of the edible films of Chen et al." and the Applicants have not identified any teachings in this reference demonstrating that Chen et al. were aware of the fact that maltodextrin is not hydrocolloids, neither accordingly the Applicants identified any teachings motivating to consider maltodextrin as an equivalent to the hydrocolloids, so that the supposed "admission" as set forth by the Office is indeed groundless and, at a minimum, the result of a ***hindsight*** reconstruction of the claimed invention, which is not admissible.

Indeed, the skilled person, while considering the reference as a whole, only knows that Chen et al. teach a "dosage unit comprising a mucosal surface-coat-forming film, wherein the mucosal surface-coat-forming film comprises a water-soluble hydrocolloid, an effective dose of a sexual dysfunction active agent and a mucosal adhesion enhancer" [emphasis added] (see e.g. claim 1, Chen et al.) so that the actual and true teaching of Chen et al. is that hydrocolloids are essential, even in an amount up to 99%, as already acknowledged also by the Office (pp. 5-6, bridging par., Office Action, October 22, 2010, "OA2"). Failing to consider a reference as a whole in making an obviousness rejection is an error by the Office, MPEP 2141.02, and the rejection cannot stand for this reason as well.

Moreover, if Chen et al. dosage unit was modified to exclude hydrocolloids, as in the current invention, the modification would render said dosage unit unsatisfactory and inoperable for its intended purpose of overcoming the problems caused by "the mobility of the dosage unit within the mouth." (see par. [0024]). This, too, also counsels against a finding of obviousness. MPEP 2143.01

Applicants' foregoing position is also valid even in the hypothetical case where the person of ordinary skill in the art would consider maltodextrin as an equivalent to hydrocolloids, according to the Office's position. In fact, exactly in view of said hypothetical equivalence the person of ordinary skill in the art would have derived that maltodextrin has the same characteristics as hydrocolloids, ***including its drawbacks***. As a matter of fact, still following the hypothetical equivalence between maltodextrin and hydrocolloids as asserted by the Office, it should also be supposed, accordingly, that since hydrocolloids tend to gel on contact with saliva (p.1, line 18, of the specification) so as to negatively affect the clean mouth sensation, maltodextrin should at the least have the same drawback. It, therefore, follows that the skilled person would be led to believe that an edible film should be free of hydrocolloids as well as free of maltodextrin. Therefore, the skilled person wishing to avoid the use of hydrocolloids,

similarly would have also wished to exclude maltodextrin from the edible films. Thus, the person of ordinary skill in the art would have never achieved the claimed invention, i.e. even hypothetically acknowledging the Office's interpretation of the reference.

This reasoning based on the Office's view thus generates a clear **teaching away** from the claimed invention because "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the [Applicant]." *Tec Air Inc. vs. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1360 (Fed Cir. 1999). In this case, a skilled person, upon reading Chen et al. as done by the Office, would be clearly led in a direction divergent from the path that was taken by the Applicants. That a reference teaches away is sufficient on its own to defeat a *prima facie* case of obviousness. See *Winner Int'l Royalty Corp. vs. Wang*, 202 F.3d 1340, 1349-50 (Fed Cir. 2000).

It follows that the obviousness rejection is erroneous because there is no motivation to select and modify the cited art dosage unit to achieve the claimed film free of hydrocolloids, much less with any reasonable expectation of success.

The fact that Barkalow et al. indistinctly list a large number of film formers, such as maltodextrin and many hydrocolloids, does not change the above reasoning.

As a matter of fact, still following the hypothetical equivalence between maltodextrin and hydrocolloids as asserted by the Office, the skilled person hypothetically combining the cited references, would, in any event, be led to believe that an edible film should be free of hydrocolloids as well as free of maltodextrin, thus being at most motivated ***to search among other film formers listed by Barkalow et al.***. This reasoning based on the Office's view thus generates an even stronger **teaching away** from the claimed invention, when applied to the combination of the cited references, because "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the [Applicant]." *Tec Air Inc. vs. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1360 (Fed Cir. 1999). In this case, a skilled person, upon reading Barkalow et al. in view of Chen et al. as done by the Office, would be clearly led in a direction divergent from the path that was taken by the Applicants, e.g. led to try film formers different from both hydrocolloids and maltodextrin. That a reference teaches away is sufficient on its own to defeat a *prima facie* case of

obviousness. See *Winner Int'l Royalty Corp. vs. Wang*, 202 F.3d 1340, 1349-50 (Fed Cir. 2000).

However, keeping in mind that there is not actual support for the Office's interpretation of Chen et al., the Office has also failed to provide any scientific reasoning or evidence to explain how the dosage unit of Chen et al. that comprise up to 99 wt% of hydrocolloids makes obvious a film **free of hydrocolloids.**

Furthermore, the Office has provided no scientific reasoning or evidence to explain how the dosage unit of Chen et al. that can comprise up to 99 wt% of hydrocolloids when hypothetically combined with the edible thin film of Barkalow et al. comprising film-formers, fillers, plasticizers, emulsifiers, flavors, ecc., would result in self-supporting films **consisting essentially of**: a) between 40 and 80% by weight of a filmogenic substance consisting of a maltodextrin, b) between 15 and 55% by weight of a plasticiser, c) between 0.05% and 30% by weight of an active ingredient for food or pharmaceutical use, on the total weight of said films, wherein said films are **free from hydrocolloids**, especially considering that the Office affirmed (p. 6, OA2):

> Chen et al. do not teach a specific embodiment comprised of 40-80% maltodextrin, 15-55% of a plasticizer and 0.05-30% of an active agent.

Consequently, the rejection based on the Office's position that maltodextrin's inclusion is interpreted as a useful film forming agent as an admission by Chen et al. that, at the least, maltodextrin can be used as an equivalent to the hydrocolloids, turns out to be clearly groundless and thus should be withdrawn.

2. Rejection under 35 U.S.C. §103(a) being unpatentable over Chen et al. (US 2003/0068378)

With respect to this rejection, the Office simply refers to the arguments provided for the previous rejection (pp. 6-7, bridging par., OA3). However, the previous rejection is based on the combination of Barkalow et al. **and** Chen et al.; particularly, the Office only refers to Chen et al. stating that (p. 4, OA3):

> Chen et al. is provided as prior art in this rejection in order to disclose antiemetic pharmaceutical agents that are incorporated into edible films which can be comprised of maltodextrin, and not for any specific film forming composition. Accordingly, Chen et al. provides adequate motivation for combining with the edible films of Barkalow et al. which are disclosed as having the ability to deliver pharmaceutical actives.

Therefore, the Office failed to support the rejection based only on Chen et al., since indeed, on considering the previous rejection, the Office only discussed the combination with Barkalow et al..

Thus, the Applicants reaffirm the non-obviousness of the claimed invention over Chen et al. alone, in view of the arguments as set forth in the responses of record (especially pp. 9-13, Reply, April 21, 2011)

In view of the above, and as supplemented by Applicants' responses of record, the pending Claims are not obvious under any of the obviousness rejections posited. If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *In re Fine, 837 F.2d 1071* (Fed. Cir. 1988); see also M.P.E.P. § 2143.03.

Withdrawal of all rejections is, therefore, respectfully requested and the issuance of a Notice of Allowance is respectfully solicited.

Please charge any fees which may be due and which have not been submitted herewith to our Deposit Account No. 01-0035.

Respectfully submitted,

Attorneys for Applicant

Date November 29, 2011

By _____

Attorney for Applicant
Reg. No.